

**REMARKS**

Reconsideration of this application is respectfully requested.

Applicants have amended claim 22 to recite "HIV-2 ROD nucleic acid" and to remove the reference to deposit I-627. No new matter enters through this amendment.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claims 22-25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. The Examiner contends that the claimed "clone does not correspond to a full-length replication competent clone" and that it "could encode none, one or more open reading frames." (Office Action at 5-6.)

Applicants traverse the rejection. The Examiner's assertion that applicants' clone might not encode an open reading frame is unsupported. The Examiner has no reason to doubt that applicants' clone encodes at least one open reading frame. **If the Examiner is relying on personal knowledge to support this allegation, applicants request that the Examiner provide an affidavit or declaration in support of this allegation. See 37 C.F.R. § 1.104(d)(2).**

Moreover, applicants' claims, as amended, recite "HIV-2 ROD nucleic acid." HIV-2 ROD is an isolate of HIV-2 deposited at the C.N.C.M. under Accession No. I-532. (Specification at 3.) This virus was isolated by propagation on normal human lymphocyte cultures. (*Id.*) Thus, there can be no doubt that this virus is replication competent. Otherwise, it could not have been propagated on normal human

lymphocyte cultures. Consequently, HIV-2 ROD nucleic acid corresponds to a full-length replication competent clone.

In addition, as objective evidence of the ability of HIV-2 ROD to replicate, applicants submit herewith a copy of a paper by Clavel et al. (Exhibit 1). This paper shows the ability of HIV-2 ROD to replicate in a CEM cell line. (Clavel et al. at 691-692.) Accordingly, the Examiner's contention that applicants' clone might be defective is in error.

Since HIV-2 ROD is a replication competent isolate, its nucleic acid must include open reading frames for viral proteins required for viral replication. The Examiner has provided no evidence to the contrary.

Moreover, as objective evidence of the presence of open reading frames for viral proteins required for viral replication of HIV-2 ROD, applicants submit herewith a copy of a paper by Guyader et al. (Exhibit 2), which shows the open reading frames of the HIV-2 ROD isolate. (Guyader et al. at 663, Fig. 1.) As is evident from Fig. 1, nearly every fragment of the genome of HIV-2 ROD comprises an open reading frame. *Id.* Accordingly, the Examiner's contention that applicants' clone might not encode an open reading frame is in error.

Furthermore, applicants provided a restriction map of the complete genome of HIV-2 (Specification at Fig. 3A.) The restriction map shows the sites for *Bam*HI, *Eco*RI, *Hind*III, *Kpn*I, *Pst*I, *Pvu*II, *Sac*I, and *Xba*I. (*Id.*) Based on applicants' disclosure of the restriction map of the complete genome of HIV-2, the skilled artisan would recognize that applicants had possession of nucleic acid fragments of HIV-2 encompassing the complete genome. Based on the further teachings of the specification, the skilled

artisan would also understand that applicants' had possession of the claimed method of using HIV-2 nucleic acid fragments to produce HIV-2 peptides.

For example, the specification explicitly teaches that polypeptides can be produced by expression of HIV-2 sequences in hosts, such as bacteria, yeast, or animal cells:

In addition, **the genetic sequences of the HIV-2 virus may be used to create the polypeptides** encoded by these sequences. Specifically, these polypeptides may be created by expression of the cDNA obtained according to the teachings herein in hosts such as bacteria, yeast or animal cells.

(Specification at 17, lines 21-25.) Thus, the skilled artisan would recognize that applicants had possession of the claimed method for producing an HIV-2 peptide. Accordingly, applicants respectfully request withdrawal of the rejection.

Applicants respectfully submit that this application is in condition for allowance. In the event that the Examiner disagrees, he is invited to call the undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: March 3, 2005

By: \_\_\_\_\_

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